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# Guidance for Industry

## How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

## Final Guidance

This final guidance describes how to use e-mail to submit a request for a meeting or teleconference to the Office of New Animal Drug Evaluation (ONADE) at the Center for Veterinary Medicine (CVM or the Center).

E-mail submissions that follow this final guidance will be compatible with CVM's current information technology capabilities. This will help ensure the confidentiality, integrity, security, and authenticity of data submitted to the Center. If a regulated company or person wishes to use an electronic approach other than that set forth in this final guidance document, the Center will, on request, discuss alternative methods of submitting a request for a meeting or teleconference.

Comments and suggestions regarding this document should be sent to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fisher's Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. 00D-1316.

For questions regarding this final document, contact Janis R. Messenheimer, Center for Veterinary Medicine, (HFV-135), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-7578, E-mail: jmessenh@cvm.fda.gov.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Veterinary Medicine**
**February 1, 2001**

00D-1316

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# GUIDANCE FOR INDUSTRY[1]

# HOW TO USE E-MAIL TO SUBMIT A REQUEST FOR A MEETING OR TELECONFERENCE TO THE OFFICE OF NEW ANIMAL DRUG EVALUATION

***This final guidance represents FDA's current thinking on this matter. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of the applicable statutes and regulations.***

## I. BACKGROUND

On request, CVM will hold meetings and/or teleconferences to assist new animal drug sponsors (sponsors) with new animal drug submissions of required data or information to support a New Animal Drug Approval.

Currently, sponsors submit paper copies of requests for a meeting or teleconference. CVM is publishing this final guidance to give sponsors the option to submit a request for a meeting or teleconference as an e-mail attachment by the Internet.

The electronic submission of a request for a meeting or teleconference is part of the Center's ongoing initiative to provide a method for paperless submissions.

This final guidance implements provisions of the Government Paperwork Elimination Act, Pub. L. No. 105-277, 112 Stat. 2681 (1998), which requires that executive agencies, by October 21, 2003, provide: (1) for the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures when practicable.

This final document contains specific instructions for submitting a request for a meeting or teleconference. Final guidance #108, How to Use E-Mail to Submit Information to CVM, contains general instructions and specifications on submitting information electronically to CVM by e-mail. It is available on the CVM Home Page. Sponsors should first register and follow the instructions in guidance #108 before submitting a request for a meeting or teleconference about New Animal Drug submissions as an e-mail attachment.

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[1] This final guidance and form have been prepared by CVM at FDA. For additional copies of this final guidance and form, access the document on the Internet by connecting to the CVM Home Page at http://www.fda.gov/cvm, or send a request to the Communications Staff, HFV-12, 7500 Standish Place, Rockville, MD 20855.

## II. CHECKLIST FOR SUBMITTING A REQUEST FOR A MEETING OR TELECONFERENCE USING ADOBE®ACROBAT® 4.0[2]

A sponsor submitting an electronic request for a meeting or teleconference should send the request as a single Portable Document Format (PDF) file attached to an e-mail. This checklist describes the process sponsors should follow to create a PDF file using a word processing program, print it to the Acrobat® Distiller, and submit the information. The PDF file can be created using other software.

1. Use a word processing software package to create a document following the form and containing the information requested in Section III of this guidance.
2. Make sure Acrobat® Distiller is selected as the default printer.
3. Fill in all pertinent sections of FDA Form #3489, the request for a meeting or teleconference form.
4. Print the word processing document to Acrobat® Distiller to create a PDF file.
5. Name the PDF file using an 8.3 file naming convention. Save the PDF file in the appropriate directory location and close the file.
6. Open the PDF file in Adobe® Acrobat® 4.0, select "Save As" and select the "Security" options for "Specify Password To: Open the Document". Enter your password and click OK. Verify the password by entering it again and then "Save" the PDF file.
7. Open your e-mail program and begin a new message.
8. Address it to cvmdcu@cvm.fda.gov.
9. Type the seven character word **MEETING** in the subject line, using all capital letters. Do not include any other punctuation or information in the subject line.
10. Do not type anything in the body of the message.
11. Attach the PDF file of the request for a meeting or teleconference to the e-mail message.
12. Send the e-mail message.
13. If you have not received an acknowledgment receipt from CVM (stars@cvm.fda.gov) within three working days after you have sent the submission, call the Electronic Document Control Unit at 301-827-8277 to report the problem and find out what happened to your submission.

After review of the agenda and proposed dates, CVM will contact the sponsor to finalize details of the meeting.

## III. REQUEST FOR A MEETING OR TELECONFERENCE FORM

A copy of the FDA Form #3489 for an electronic request for a meeting or teleconference follows.

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[2] This checklist uses Adobe Acrobat 4.0 for the purpose of example. FDA use of specific products does not constitute endorsement of those products. Sponsors may use other software to create files.

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>Food and Drug Administration<br>Center for Veterinary Medicine | **REQUEST FOR A MEETING OR TELECONFERENCE** | Form Approved: OMB No. 0910-0452<br>Expiration Date: 11/30/2003 |
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**PAPERWORK REDUCTION ACT STATEMENT:** A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a current valid OMB control Number. The public reporting burden for the collection of information is estimated to average 41 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Food and Drug Administration, Center for Veterinary Medicine, HFV-6, 7500 Standish Place, Rockville, MD 20855.

***Submit this notice electronically to:***
**Food and Drug Administration**
**Center for Veterinary Medicine (HFV- )**
**7500 Standish Place**
**Rockville, Maryland 20855**
**(E-mail:cvmdcu@cvm.fda.gov)**

DATE:
INAD / NADA NO:
DRUG:
SPECIES:

The sponsor, , submits a request for a meeting or teleconference.
This information is submitted in electronic form.

## I. Request:

1. PROPOSED DATE(S) AND TIME(S):
2. SPONSOR PARTICIPANTS:

3. REQUESTED CVM PARTICIPANTS:

4. TYPE OF MEETING
   ☐ In Person Conference ☐ Teleconference ☐ Video Teleconference
   ☐ Other(specify):

5. AUDIO-VISUAL REQUIREMENTS:
   ☐ Slides ☐ Overhead ☐ Computer Projection
   ☐ Other(specify):

## II. Sponsor Information

1. SPONSOR'S NAME:
2. SPONSOR'S ADDRESS:

3. SPONSOR CONTACT'S NAME:
4. SPONSOR CONTACT'S PHONE NUMBER:
5. SPONSOR CONTACT'S FAX NUMBER:
6. SPONSOR CONTACT'S E-MAIL ADDRESS:

## III. Itemized Agenda (Attached):